NOV 20 2012

SECTION 5 510(k) Summary

Submitter's Name:	Torrey Spine
Submitted on behalf of:	FAIRWAY MEDICAL Co., Ltd. 54-4 NONHYUN-DONG, ILSIM BLDG #308 GANGNAM-GU SEOUL Republic of Korea
Submitter's Address:	12707 High Bluff Dr. Suite 200 San Diego, CA 92130
Submitter's Telephone:	Phone 858-779-1370 Fax 858-408-3326
Contact Name:	Jason Yim
Date Summary was Prepared:	05/10/2012
Trade or Proprietary Name:	VICEROY Spinal System
Common or Usual Name:	Pedicle Screw Spinal System
Classification:	Class III per 21 CFR §888.3070
Product Codes:	MNI, 21 CFR 888.3070, Pedicle screw spinal system MNH, 21 CFR 888.3070, Pedicle screw spinal system NKB, 21 CFR 888.3070, Pedicle screw spinal system
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Device Names: ACME Spinal System, 510(K) Number: K071824 Moss Miami and Expedium Spinal System, 510(K) Number: K103490 & K955348

SUBSTANTIAL EQUIVILENCE

The VICEROY Spine System is substantially equivalent to the ACME Spinal System (K071824), DePuy Moss Miami and Expedium Spinal System (K103490 & K955348). The VICEROY Spine system is equivalent to the predicate systems with respect to materials, design, indications for use, and operational principles. There are no substantial differences between the subject device and the predicate devices and thus no differences which could affect safety or efficacy. Based on a comparison of testing between the subject and predicate devices, FAIRWAY Medical Co., LTD believes the VICEROY Spine System is substantially equivalent to the predicate devices.

PERFORMANCE SUMMARY

Testing was performed to support the equivalence of the proposed pedicle screw system in accordance with FDA Guidance "Guidance for Industry and FDA Staff: Spinal System 510(k)s." The following testing was performed in accordance with ASTM F1717: static compression bending, static torsion, and dynamic compression bending.

DESCRIPTION OF THE DEVICE

The VICEROY Spine System consists of four or more pedicle screws and two VICEROY solid rods in a symmetric, bilateral arrangement. The pedicle screws are placed axially in the pedicles with two screws in the cephalad position and two screws in the caudad position. The VICEROY rods are secured in the heads of the pedicle screws so that fixed stabilization is provided between the cephalad and caudad vertebrae. Cross-links can be used if additional stabilization is necessary. The VICEROY Spine System is fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136, *Standard Specifications for Wrought Titanium-6Aluminum-4VanadiumELI (Extra Low Interstitial) Alloy or Surgical Implant Applications*.

INDICATIONS FOR USE

When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the VICEROY Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis, (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 20, 2012

Torrey Spine
% Empirical Testing Corporation
Ms. Meredith May
Validation, Certification and Technical Specialist
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K122229
Trade/Device Name: VICEROY Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: October 31, 2012
Received: November 1, 2012

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 Indication for Use

510(k) Number (if known): Device Name: VICEROY Spine System

When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the VICEROY Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis, (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ed Keith

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K122229